

WHAT IS CLAIMED IS:

1. A stentless prosthetic heart valve, comprising:
a plurality of thin, flexible leaflets, each of the leaflets having an inner face, an outer face, an in-flow edge, an out-flow edge, and side edges, the plurality of leaflets being sewn together along at least a portion of their side edges so as to form a substantially tubular valve structure having an in-flow end and an out-flow end, adjacent leaflets being arranged so that their side edges are substantially aligned and the inner faces of the leaflets engage each other adjacent the side edges,
- 5
- 10 wherein the valve structure is movable between a closed position in which the out-flow edges of adjacent leaflets engage each other, and an open position in which the out-flow edges of adjacent leaflets are separated from each other except along the side edges, the sewn portions of the side edges of the leaflets biasing the leaflets toward a partially closed position.
- 15 2. A heart valve as in Claim 1, wherein the aligned leaflet side edges extend generally outwardly from the substantially tubular valve structure.
3. A heart valve as in Claim 1, wherein each of the leaflets comprises a tab portion adjacent the leaflet out-flow edge.
4. A heart valve as in Claim 3, wherein each tab portion extends beyond the
- 20 out-flow edge of the corresponding leaflet.
5. A heart valve as in Claim 3, wherein the tab portions are disposed adjacent at least one of the leaflet side edges.
6. A heart valve as in Claim 5, wherein a tab portion is formed adjacent each leaflet side edge.
- 25 7. A heart valve as in Claim 6, wherein the tab portions of adjacent leaflets are connected to each other to form commissural attachment tabs.
8. A heart valve as in Claim 7, wherein the connected tab portions are at least partially folded over each other.
9. A heart valve as in Claim 7 additionally comprising reinforcement
- 30 material over the commissural attachment tabs.

10. A heart valve as in Claim 7, wherein the commissural tabs extend distally beyond the out-flow end of the tubular valve structure.

11. A heart valve as in Claim 6, wherein each commissural tab substantially lies in a plane generally tangential to the tubular valve structure when the valve structure is in the open position.

12. A heart valve as in Claim 1, wherein each of the leaflets are substantially identical.

13. A heart valve as in Claim 1 comprising a first leaflet and a second leaflet, and a width of the in-flow edge of the first leaflet is greater than a width of the in-flow edge of the second leaflet.

14. A heart valve as in Claim 13, wherein a width of the out-flow edge of the first leaflet is substantially the same as a width of the out-flow edge of the second leaflet.

15. A heart valve as in Claim 1 additionally comprising a cloth reinforcement member attached to the valve in-flow end.

16. A stentless semilunar heart valve, comprising:
three thin, flexible leaflets, each of the leaflets having an inner face, an outer face, an in-flow edge, an out-flow edge, side edges, and tab portions extending outwardly beyond the side edges and positioned adjacent the out-flow edge, the leaflets being attached to each other along their side edges so as to form a substantially tubular valve structure having an in-flow end and an out-flow end;

wherein the tab portions of adjacent leaflets engage each other to form commissural attachment tabs, at least a portion of each commissural attachment tab being adjacent the outer faces of the adjacent leaflets.

17. A semilunar heart valve as in Claim 16, wherein the three leaflets are substantially identical to each other.

18. A semilunar heart valve as in Claim 16, wherein adjacent leaflets are arranged so that their side edges are substantially aligned and the leaflet inner faces engage each other adjacent the side edges, and a plurality of stitches are disposed along a line adjacent the aligned side edges.

19. A semilunar heart valve as in Claim 18, wherein a portion of the line adjacent the out-flow edges of the leaflets has no stitches therein.

20. A semilunar heart valve as in Claim 16, wherein the tab portions of adjacent leaflets overlap each other so that each commissural tab has multiple layers.

5 21. A semilunar heart valve as in Claim 20 additionally comprising a cloth reinforcement member attached to the commissural attachment tabs.

22. A semilunar heart valve as in Claim 16, wherein a diameter of the in-flow end of the valve structure is greater than a diameter of the out-flow end of the valve structure.

10 23. A semilunar heart valve as in Claim 16, wherein the in-flow edge and out-flow edge of each leaflet has a substantially scalloped shaped.

24. A semilunar heart valve as in Claim 23, wherein a center portion of the in-flow edge of each leaflet extends a distance proximal of a position at which the side edge meets the in-flow edge.

15 25. A semilunar heart valve as in Claim 24, wherein a center portion of the out-flow edge of each leaflet extends a distance distal of a position at which the side edge meets the out-flow edge.

26. A stentless heart valve, comprising:

20 a first leaflet comprising a leaflet main body having an inner face, an outer face, a proximal end, a distal end, a first side edge, and a first tab portion adjacent the distal end and extending from the first side edge, the first tab portion connected to the first leaflet main body through a first neck portion; and

25 a second leaflet comprising a leaflet main body having an inner face, an outer face, a proximal end, a distal end, a second side edge, and a second tab portion adjacent the distal end and extending from the second side edge, the second tab portion having a longitudinal slot and connected to the second leaflet main body through a second neck portion;

30 the first side edge of the first leaflet and the second side edge of the second leaflet being substantially aligned with and attached to one another and the inner faces of the first leaflet and the second leaflet engaging each other adjacent the aligned side edges; and

wherein the second tab portion is folded so that the first and second neck portions extend through the longitudinal slot of the second tab portion.

27. A heart valve as in Claim 26, wherein the first tab portion is folded over the second tab portion.

5 28. A heart valve as in Claim 26, wherein the first and second neck portions are not stitched.

29. A heart valve as in Claim 26, wherein the first and second tab portions are sewn together to form a commissural attachment tab.

10 30. A heart valve as in Claim 29, wherein the commissural attachment tab is adapted to be attached to an inner wall of a blood vessel.

31. A heart valve as in Claim 26, wherein the tabs, neck and main body of each leaflet are unitarily formed.

32. A heart valve as in Claim 26, wherein the proximal and distal ends of the leaflet are scalloped.

15 33. A method for making a stentless tubular prosthetic heart valve, comprising:

providing a section of substantially flat, flexible material;

20 cutting a plurality of leaflets out of the flat material, each of the leaflets having an inner face, an outer face, a proximal end, a distal end, side edges, and tab portions adjacent the distal end and extending from the side edges;

aligning the side edges of adjacent leaflets together so that the inner faces of adjacent leaflets engage each other adjacent the side edges; and

sewing aligned side edges together so as to form a substantially tubular valve structure having an in-flow end and an out-flow end.

25 34. The method of Claim 33, wherein providing a section of substantially flat, flexible material involves providing a section of pericardium and fixing the pericardium.

35. The method of Claim 34, wherein the material is equine pericardium.

30 36. The method of Claim 33, wherein cutting a plurality of leaflets is accomplished using a non-contact cutting apparatus.

37. The method of Claim 37, wherein cutting a plurality of leaflets is accomplished using a laser.

38. The method of Claim 33 additionally comprising folding the tab portions of the leaflets to form a commissural tab.

5 39. A method of manufacturing a prosthetic heart valve comprising:
providing a first valve leaflet and a second valve leaflet, the leaflets being formed separately from each other;
placing a portion of an inward face of the first valve leaflet against a corresponding portion of an inward face of the second valve leaflet; and
10 attaching the inward face portions to each other.

40. The method of Claim 39, wherein the inward face portions of the leaflets are attached at the side edges of the leaflets.

41. The method of Claim 39 additionally comprising forming the valve leaflets from equine pericardium.

15 42. A method of manufacturing a prosthetic valve comprising:
providing first and second valve leaflets each having an integral tab portion at an end thereof; and
folding the tab portions relative to each other to provide a commissural tab, the commissural tab being attached to the leaflets along a commissural tab
20 line such that free ends of the tabs extend outwardly from the line.

43. The method of Claim 42 additionally comprising attaching side edges of the valve leaflets to each other along an attachment line which is coextensive with the commissural tab line.

25 44. A prosthetic valve comprising:
a plurality of valve leaflets comprised of a flexible material, each leaflet having an inner surface and an outer surface, each leaflet attached to another leaflet along an attachment line, a portion of an inner surface face of one leaflet being in facing relationship with a portion of an inner surface of another leaflet at the attachment line; and

30 a commissural tab at an end of each attachment line, said tab having free ends configured for attachment to a blood vessel.

45. The valve of Claim 44, wherein the commissural tab is comprised of a flexible material.

46. The valve of Claim 44, wherein the commissural tab is integral with the valve leaflet.

5 47. The valve of Claim 44, wherein the leaflets are comprised of pericardial tissue.

48. The valve of Claim 47, wherein the leaflets are comprised of equine pericardium.

FOIA b 7 - D